K061384

JUN - 6 2006

W.LORENZ SURGICAL
A Biomet Company

# 510(k) Summary

**1520 Tradeport Drive**
**Jacksonville, FL 32218**
**904-741-4400 fax 904-741-4500**

**Device Name:** Lorenz Pectus Support Bar System

**Classification Name and Reference:** Plate, Fixation, Bone 87 HRS (CFR 888.3030)

**Device Classification:** Class II

**Device Description:** Pectus Pre-bent Support Bar: A stainless steel or titanium bar, variable length from 7 to 17 inches, and 0.50 inches wide, with two holes and notches on both ends for sutures to secure the bar to the lateral chest wall. The bar is pre-shaped based on a CT Scan provided by the Surgeon specifically for a certain patient. The titanium bar is only used when the patient has a nickel allergy.

Pectus Titanium Support Bar Stabilizer: A titanium elongated plate with a dovetail slot in the center of the plate for the Pectus Bar to slide into. Two lips come up over the bar to secure the Pectus Bar within the slot of the stabilizer. The stabilizers have two holes on either side of the slot to suture the stabilizer to the lateral chest wall together with the support bar preventing lateral movement and flipping of the bar.

**Intended Use:** This device is intended for use in surgical procedures to repair Pectus Excavatum and other chest wall deformities.

**Materials:** Stainless Steel or Titanium

**Possible Adverse Effects:**
1. Metal sensitivity reactions or allergic reaction to the implant material.
2. Pain, discomfort, or abnormal sensation due to the presence of the device.
3. Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.
4. Skin irritation, infection, and pneumothorax.
5. Fracture, breakage, migration, or loosening of the implant.
6. Inadequate or incomplete remodeling of the deformity or return of deformity, prior to or after removal of implant.
7. Permanent injury or death.

**Substantial Equivalence**
The Pectus Pre-bent Support Bar made of either Stainless Steel or Titanium and the Pectus Titanium Support Bar Stabilizer is believed to be substantially equivalent in application and function to:

Lorenz Pectus Support Bar Stabilizer (K981789)
Lorenz Pectus Support Bar (K972420)

**Statement of Comparison of Technological Features**
Both the predicate and the new (contained within this submission) devices consist of non absorbable material (stainless steel, titanium) listed in FDA's Biomaterials Compendium and list of FDA recognized standards. The metallic materials and the intended use are technically equivalent. The modified devices are being added to:

1. address the nickel sensitivity of some patients and
2. to address surgeon preference of receiving the Pectus Support Bar pre-bent.

**Conclusions:** The use of the modified devices and the predicate Pectus Support Bar and Stabilizer are substantially similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

W. Lorenz Surgical
% Ms. Kim Reed
Senior Regulatory Specialist
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K061384
Trade/Device Name: Lorenz Pectus Support Bra System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulation Class: II
Product Code: HRS
Dated: May 17, 2006
Received: May 18, 2006

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: Lorenz Pectus Support Bar System

Indications For Use: This device is intended for use in surgical procedures to repair Pectus Excavatum and other chest wall deformities.

Prescription Use __xx_____ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K061384